REMARKS

Claims 1-29 are pending and subject to restriction in the above-identified application.

Applicants request consideration and entry into the record of the following amendments and remarks.

Restriction Requirement

In the April 11, 2008 Office Action, the Examiner has required restriction of claims 1-29 of the present invention to one of five groups, identified as Groups 1 to 5:

Group 1: Claims 1, 2-13 and 23-25, in part, drawn to the compound of Formula (I), where R2 and W are non-heterocyclic ring systems;

Group 2: Claims 1, 2-12, 14 and 23-25, in part, drawn to the compound of Formula (I), where R2 and W are heterocyclic ring systems;

Group 3: Claims 21, 22 and 29, in part, where R2 and W are non-heterocyclic ring systems, drawn to the method for treating a condition characterized by under-activation of the HM74A receptor;

Group 4: Claims 21, 22 and 29, in part, where R2 and W are heterocyclic ring systems, drawn to the method for treating a condition characterized by under-activation of the HM74A receptor; and

Group 5: Claims 26-28, drawn to the process for preparing the compound of Formula (I).

The Examiner states that:

> "the inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature linking the claims is a compound of Formula (I)."

In response to the restriction requirement, applicants provisionally elect, with traverse, to prosecute:

Group 1: Claims 1, 2-13 and 23-25, in part, drawn to the compound of Formula (I) where R2 and W are non-heterocyclic ring systems.

Applicants respectfully traverse based upon the following reasons:

In accordance with PCT Practice:

PCT Rule 13.1 states that international application shall relate to one invention only or to a group of inventions so linked as to form a single general concept (i.e., "requirement of unity of invention").

PCT Rule 13.2 states that unity of invention shall be fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art".

Further, M.P.E.P. Section 1850 and 37 C.F.R § 1.475 states that:

"(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."

In accordance with U.S. Practice, M.P.E.P. §§§ 802.01, 802.02 and 803 state that: "Under M.P.E.P. 808.02, "the Examiner in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required. Thus the examiner must show by appropriate explanation one of the following:

(A) Separate classification thereof: . .
(B) A separate status in the art when they are classifiable together. . ..
(C) A different field of search . . .

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions.

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions."

In light of the above, applicants respectfully maintain that Examiner has not provided sufficient evidence or reasons to establish why restriction is proper or to show why a serious search burden would be imposed upon examination of the claimed invention for the following reasons.

[1] Lack Of Unity Under PCT Rules 13.1 And 13.2 Not Held During PCT Examination Of The Identical Corresponding Application To The Present Invention.

Claims of the present invention do not lack unity under PCT Rule 13.1 and 13.2, but have a "significant structural element" qualifying as a "special technical feature" that defines a contribution over the prior art. PCT Rule 13.1 includes within the definition of unity of invention "a group of inventions so linked as to form a general inventive concept".

Patentably distinct inventions do not lack unity of invention as long as they derive from the same inventive concept. What is required for a holding of lack of unity is that the inventions be truly "independent". This is the standard for lack of unity applied by the court in *In re Harnish*, 206 USPQ 300, 306 (CCPA 1980) ("unity of invention" ... appl[ies] where *unrelated* inventions are involved") (emphasis supplied). Independent, as defined in MPEP § 802.01, "means that there is no disclosed relationships between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect".

[2] Instant Appln Is A 35 U.S.C. 371 Appln. And Improper U.S. Restriction Practice Applied

As the instant international application has met requirements of 35 U.S.C. 371 (see, U.S.P.T.O.'s 371 Acceptance Letter of April 6, 2007), the above-identified restriction requirement set forth by the Examiner is improper for being based upon U.S. style restriction practice, instead of restriction practice in accordance with P.C.T. rules set forth in 37 C.F.R. § 1.475 and explained in M.P.E.P. Section 1850 (see, rules set forth ***supra***).

In particular, applicants respectfully submit that the U.S.P.T.O. should have considered the claimed invention drawn to anthranilic acid derivatives compounds of formula (I) to have unity of invention, such that all of the identified groups of the claimed invention should be examined together.

This is verified by the fact that Examiner has noted that "the special technical feature linking the claims is a compound of Formula (I)". Compounds of Formula (I) of the present invention are anthranilic acid derivatives of Formula (I), sharing a common structural core ring structure, which are so connected as to have arisen from a singular research effort with

common shared properties that are used for treatment of specific diseases in which under-activation of the HM74A receptor contributes to the disease, i.e., such as lipid metabolism, cardiovascular diseases (inc. cardiovascular indications associated with diabetes), inflammatory diseases, or gastrointestinal tract, lung, heart, nervous tissue, pancreatic, kidney, or eye diseases, etc. (see, instant specification at page 13, lines 4-41 to page 14, lines 1-18).

Also, as the present appln. is a 35 U.S.C. 371 Appln. and claim 1, i.e., the first recited claim invention, is directed to a compound of formula (I), which is a product, applicants respectfully point out that the U.S.P.T.O. should have considered relevant PCT rules in deciding whether restriction was necessary and grouping the claims of the invention into category combinations set forth in 37 C.F.R. § 1.475 (b), (d) and (e) (see defined above).

Based on that, representative restriction group examples of the presently claimed invention in accordance with applicable PCT rules may be as follows:

> Claims 1, 2-13, 21, 22, 29 and 23-25, 26-28 in part, drawn to the compound of Formula (I) where R2 and W are non-heterocyclic ring systems, method of treating a condition characterized by under activation of the HM74A receptor using, and process for preparing the compound of Formula (I); and
>
> Claims 1, 2-12, 14, 21, 22, 29 and 23-25, 26-28 in part, drawn to the compound of Formula (I) where R2 and W are heterocyclic ring systems, method of treating a condition characterized by under activation of the HM74A receptor using and process for preparing the compound of Formula (I).

[3] <u>No Assignment Of Individual Class And Subclasses Designations From U.S. Classification Manual To Groups 1-5, Respectively.</u>

In accordance with U.S. Patent Law, there are no reasons that exist for dividing among independent or related inventions of the present invention such that search and examination of all the claims in an application can be made without serious burden, even though they include claims to independent or distinct inventions.

Based upon the foregoing, compelling applicants to pursue the present invention in five separate applications will serve only to place additional efforts and burden on the U.S. Patent Office and applicants.

More importantly, applicants respectfully point out that the same prior art search will apply to the separate and distinct inventions of the present application such that the pending restriction requirement set forth by the U.S.P.T.O. is improper.

For the record, as elected subject matter for examination on the merits is directed to a product (i.e., compound), applicants also reserve the right to request rejoinder of

commensurate in scope non-elected subject matter or inventions (i.e., such as corresponding treatment methods, pharmaceutical compositions and processes) upon the determination of allowable subject matter (*In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996); also see MPEP § 821.04 (b)).

In light of the foregoing, applicants reserve the right to file non-elected inventions as the subject of future applications, which may derive priority from the present application, without prejudice.

Therefore, applicants respectfully request that the Examiner withdraw the above-identified restriction requirement.

CONCLUSION

In view of the above amendments and remarks, applicants believe that the claims of the present application are in condition for allowance, which is earnestly solicited.

If any additional fees or charges are required authorization is hereby granted to charge any necessary fees to Deposit Account No. 19-2570 accordingly.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,

Grace C. Hsu
Attorney for Applicants
Registration No. 51,336

GLAXOSMITHKLINE
Corporate Intellectual Property-UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone: (610) 270-4650
Fax: (610) 270-5090
n:\gch\PB60299 office action.doc